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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,651	04/17/2007	Borut Furlan	33578US-PCT	5011

1095 7590 07/09/2008

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
CHO, JENNIFER Y	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
07/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,651	FURLAN ET AL.	
	Examiner	Art Unit	
	JENNIFER Y. CHO	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *5-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is in response to Applicant's communication filed on 4/17/08.

Claims 1-10 are pending in this application.

Applicant's election with traverse of Group 1, claims 1-4 in the reply filed on 4/17/08 is acknowledged. The traversal is on the ground(s) that the Office Action has not established that it would pose an undue burden to examine the full scope of the claims. This is not found persuasive because the claims of the various groups are divergent in subject matter and are classified separately. The requirement is still deemed proper and is therefore made FINAL.

Claims 5-10 have been withdrawn from consideration, being drawn to the non-elected subject matter.

IDS

The information disclosure statement (IDS) filed on 6/26/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Objections

The title is objected to because of the following informalities: Applicant's title is believed to be misspelled and in the Examiner's opinion, would be benefited by including the words "tamsulosin" in the title. Appropriate clarification is requested.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoorn et al. (US 6,835,853).

The instant claims are drawn to tamsulosin hydrochloride containing less than 0.1% of overalkylated products.

Hoorn et al. teaches tamsulosin hydrochloride at more than a 99.9% purity.

Hoorn et al. is deficient in that it does not explicitly state the content of the possible impurities.

However, it is the position of the examiner that there is no unexpected result in the production of tamsulosin hydrochloride with less than 0.1% of overalkylated products, since the prior art teaches the same end product and starting materials. Thus it is expected that the impurities would be similar. Because the patent office is not equipped with the ability to make the determination of the amount of overalkylated products remaining in the tamsulosin hydrochloride in the prior art, the burden is shifted to the applicant to establish an unexpected result and make a comparison with the cited prior art.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to isolate tamsulosin hydrochloride containing less than 0.1% of overalkylated products. One of ordinary skill in the art would be motivated isolate pure tamsulosin hydrochloride, with the reasonable expectation that the compound would show increased potency in the treatment of cardiac insufficiencies and improved pharmacological activities. Absent any showing of unusual and/or unexpected results over Applicant's particular tamsulosin hydrochloride, the art obtains the same effect on the purity of tamsulosin hydrochloride in the prior art. Furthermore, the limitations in some of the dependent claims, not expressly taught in the art, are also deemed to be obvious. One of ordinary skill in the art would be motivated to tweak and optimize these parameters to arrive at the instantly claimed invention. The expected result would be the efficient production of tamsulosin hydrochloride for the pharmaceutical industry.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujikura et al. (AT 397 960).

The instant claims are drawn to tamsulosin hydrochloride containing less than 0.1% of overalkylated products.

Fujikura et al. teaches tamsulosin hydrochloride with an approximate 99.95 purity (calculated from the difference in elemental analysis between “calculated” and “found” on page 9, lines 19-25).

Fujikura et al. is deficient in that it does not explicitly state the content of the possible impurities.

However, it is the position of the examiner that there is no unexpected result in the production of tamsulosin hydrochloride with less than 0.1% of overalkylated products, since the prior art teaches the same end product and starting materials (page 5, lines 1-45). Thus it is expected that the impurities would be similar. Because the patent office is not equipped with the ability to make the determination of the amount of overalkylated products remaining in the tamsulosin hydrochloride in the prior art, the burden is shifted to the applicant to establish an unexpected result and make a comparison with the cited prior art.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to isolate tamsulosin hydrochloride containing less than 0.1% of overalkylated products. One of ordinary skill in the art would be motivated isolate pure tamsulosin hydrochloride, with the reasonable expectation that the compound would

show increased potency in the treatment of cardiac insufficiencies and improved pharmacological activities. Absent any showing of unusual and/or unexpected results over Applicant's particular tamsulosin hydrochloride, the art obtains the same effect on the purity of tamsulosin hydrochloride in the prior art. Furthermore, the limitations in some of the dependent claims, not expressly taught in the art, are also deemed to be obvious. One of ordinary skill in the art would be motivated to tweak and optimize these parameters to arrive at the instantly claimed invention. The expected result would be the efficient production of tamsulosin hydrochloride for the pharmaceutical industry.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho
Patent Examiner
Art Unit: 1621

/SHAILENDRA - KUMAR/
Primary Examiner, Art Unit 1621